

SEP 13 1999

NDA 20-516/S-004
NDA 20-601/S-002
NDA 20-602/S-003
NDA 20-603/S-002

McNeil Consumer Healthcare
Attention: Janet Uetz
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Uetz:

Please refer to your supplemental new drug applications dated June 1, 1998, received June 2, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, providing for revised labeling for the following products:

NDA 20-516/S-004 Children's Motrin (ibuprofen) oral suspension 100 mg/5 mL;
NDA 20-601/S-002 Children's/Junior Strength Motrin (ibuprofen) chewable tablets, 50 and 100 mg;
NDA 20-602/S-003 Junior Strength Motrin (ibuprofen) tablets, 100 mg; and
NDA 20-603/S-002 Childrens Motrin (ibuprofen) drops, 50 mg/1.25 mL.

We also acknowledge receipt of your communications dated October 23, 1998 and February 19, 1999.

We have completed the review of these supplemental new drug applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the draft labeling dated June 1, 1998. Accordingly, these supplemental new drug applications are approved effective on the date of this letter.

For each supplemental NDA, please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated as FPL for approved supplemental NDA 20-516/S-004, 20-601/S-002, 20-602/S-003, 20-603/S-002, as applicable. Approval of these submissions by FDA is not required before the labeling is used.

As agreed during the telephone conversation of February 11, 1999, between Kerry Rothschild and Willie Pagsuyuin, and confirmed in Mr. Pagsuyuin's letter of February 19, 1999, the

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following revisions in the labeling of each product will be made at the time of the next printing or within 180 days of receipt of an approval letter, whichever comes first:

1. The header "Important" should be deleted. The phrase "Do not exceed recommended dose..." should be revised to read "Do not take more than directed." This should be placed under the "Directions" section as the first bullet. The second sentence following "Do not exceed recommended dose" should be deleted.
2. The storage statement should be modified to read "Store between 20°-25°C (68°-77°F)."
3. The flag statement "See New Label" should be removed after 6 months.

You are further reminded that the "Aspirin Sensitive Children" statement should have been replaced with the "Allergy alert" statement required by the agency's letter of September 15, 1998. in accordance with the time frame outlined in that letter.

Please also reformat the labeling of these products in accordance with the provisions of the March 17, 1999 FEDERAL REGISTER document "Over-The-Counter Human Drugs; Labeling Requirements; Final Rule" (64 FR 13254).

Should additional information relating to the safety and effectiveness of these drugs become available, further revision of the labeling may be required.

This approval affects only those changes specifically submitted in these supplemental new drug applications. Other changes that may have been approved or are pending evaluation are not affected.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about any of these drug products (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to the subject NDA and a copy to the following address:

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MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding these applications, please contact Kerry Rothschild, Esq., Regulatory Project Manager, at (301) 827-2284.

Sincerely yours,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

IMPORTANT: Read all product information before using. Keep this box for important information. This product is intended for use in children only.

ACTIVE INGREDIENT: Ibuprofen.

USES: For Temporary:

- Reduction of fever
- Relief of minor aches and pains due to colds, flu, sore throat, headaches and toothaches

DIRECTIONS:

1. Shake well before using.
2. Find right dose on chart below. If possible, use weight to dose; otherwise use age.
3. Only use enclosed dropper; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek.
4. Replace original bottle cap to maintain child resistance.
5. If needed, repeat dose every **6-8 hours**.
6. Do not use more than **4 times a day**.
7. If stomach upset occurs while taking this product, give with food or milk.

WEIGHT (lb)	AGE (yr)	DOSE
Under 24	Under 2	Consult Doctor
24-35	2-3	2 Dropperfuls (2 x 1.25 mL)
One Dose Lasts 6-8 Hours		

Attention: Specially designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing device.

WARNINGS

ALLERGIC REACTIONS: Children's Motrin may cause a severe allergic reaction which may include:

- wheezing (asthma)
- shortness of breath
- hives
- swelling of the face
- fast, irregular pulse or heartbeat
- changing color of the skin (shock)

ASPIRIN-SENSITIVE PATIENTS: Although Children's Motrin does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people allergic to aspirin or other pain relievers/fever reducers. **Any of these reactions could be serious. Stop using this product and get emergency medical help immediately.** These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motrin or other pain relievers/fever reducers.

(See Side Panel to the Right for Additional Warnings) →

WARNINGS (continued)

CALL YOUR DOCTOR IF:

- Your child is under a doctor's care for any serious condition or is taking any other drug.
- Your child has problems or serious side effects from taking fever reducers or pain relievers.
- Your child does not get any relief within first day (24 hours) of treatment, or pain or fever gets worse.
- Stomach upset gets worse or lasts.
- Redness or swelling is present in the painful area.
- Sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vomiting.
- Any new symptoms appear.

DO NOT USE:

- With any other product that contains ibuprofen, or any other pain reliever/fever reducer, unless directed by a doctor.
- For more than **3 days** for fever or pain unless directed by a doctor.
- For stomach pain unless directed by a doctor.
- If your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea or lack of fluid intake.
- If plastic bottle wrap imprinted "Safety Seal®" and "Use With Enclosed Dropper Only" is broken or missing.

(See Opposite Side Panel for Additional Warnings) →

For Ages 2-3

Children's Motrin®

CONCENTRATED Drops

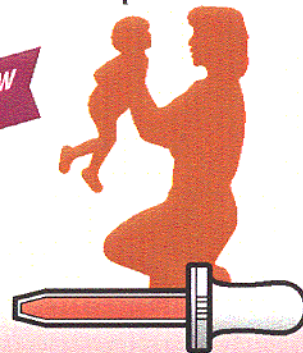
IBUPROFEN ORAL SUSPENSION

50 mg per 1.25 mL (dropperful)

Fever Reducer/Pain Reliever

Lasts up to **8 hours**

See New
Label



Use Only
With
Enclosed
Dropper

BERRY-FLAVORED DROPS

Alcohol Free

1/2 fl oz (15 mL)

WARNINGS (continued)

IMPORTANT:

- Do not exceed recommended dose. Taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems. **Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.**

Questions or Comments?

Call toll free

1-800-962-5357

Or ask your Pharmacist,
Doctor or other Health Care
Professional.

See bottom of box for lot
number and expiration date.

Store at room temperature:
15°-30°C (59°-86°F)

Inactive Ingredients: Citric acid, cornstarch, FD&C Red #40, artificial flavors, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum.

McNEIL

McNEIL CONSUMER PRODUCTS CO.
DIVISION OF McNEIL-PPC, INC.
FORT WASHINGTON, PA 19034 USA
©McN-PPC, Inc. '98
U.S. Patent No. 5,374,659

FPO

Do not use if plastic bottle wrap
imprinted "Safety Seal®" and
"Use With Enclosed Dropper
Only" is broken or missing.

Children's Motrin®

CONCENTRATED Drops

Ibuprofen Oral
Suspension
50 mg per 1.25 mL
(dropperful)

1/4 fl oz (7.5 mL)

WARNINGS—ALLERGIC REACTIONS: Children's Motrin may cause a severe allergic reaction which may include: wheezing (asthma); shortness of breath; hives; swelling of the face; fast, irregular pulse or heartbeat; or changing color of the skin (shock). **ASPIRIN-SENSITIVE PATIENTS:** Although Children's Motrin does not contain aspirin, it may cause a severe reaction, similar to that listed above, in people allergic to aspirin or other pain relievers/fever reducers. **Any of these reactions could be serious. Stop using this product and get emergency medical help immediately.** These reactions can occur after taking a single dose or any subsequent dose in persons both with, and without, prior reaction to Children's Motrin or other pain relievers/fever reducers. **IMPORTANT:** See box for complete **WARNINGS** and other information and **save box for future use.** **USES:** For Temporary: Reduction of fever and relief of minor aches and pains due to colds, flu, sore throat, headaches and toothaches. **DIRECTIONS:** 1. Shake well before using. 2. Find right dose on chart below. If possible, use weight to dose; otherwise use age. 3. Only use enclosed dropper; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek. 4. Replace original bottle cap to maintain child resistance. 5. If needed, repeat dose every **6–8 hours**. 6. Do not use more than **4 times a day**. 7. If stomach upset occurs while taking this product, give with food or milk. **Store at room temperature: 15°–30°C (59°–86°F).**

Weight (lb)	Age (yr)	Dose
Under 24	Under 2	Consult Doctor
24–35	2–3	2 Dropperfuls (2x1.25 mL)

Exp. Date:

Control:

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